U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

HRTD Human Resources Training & Development

R&D/Laboratory Inspections

R&D/Laboratory Inspections

- aka -

Inspecting users and uses of <u>unsealed</u> radioactive materials in non-medical activities [typically found in research-type facilities such as universities, pharmaceutical companies, military facilities, or analytical laboratories; and sometimes at manufacturing/processing plants, veterinary facilities, and other places]

typical ‘unsealed’ activities

- Basic Research
- Technology Development
- Teaching
- Analytical services for others

Does ***NOT*** include

- human research (Part 35 – medical use)

Inspection References

- The license; the licensee's application; and/or amendment document(s).
- 10 CFR 20, 30, 32, 33, etc or state equivalents
- NUREG-1556 guidance series
  - Vol. 7: Academic, Research & Development and Other Licenses of Limited Scope (including G.C. and X.R.F.) December 1999
  - Vol. 11:…Licenses of Broad Scope
  - Vol. 12:…Licenses for Manufacturing…
  - others

Inspection Procedures

References

- Inspection Procedure (IP) 87125 Materials Processor/Manufacturer Programs
- Inspection Procedure (IP) 87126 Industrial/Academic/Research Programs

Typical ‘unsealed’ RAM (CHIPS)

Carbon 14

Hydrogen 3

Iodine 125 & 131

Phosphorus 32 & 33

Sulfur 35

Less Commonly Used RAM

Cl-36, Ca-45, Cr-51, or other 'low-E' β +/-

Rb-86, Sr-90 or other 'high-E' β

Sr-85, Nb-95 (microspheres) or other γ

Tc-99m, F-18, and other RAM for non-human use medical research

Uranium or thorium or other alpha emitters

Small quantities, small volumes

Uses of ‘Unsealed’ RAM

- Bench top “wet chemistry” using pre- labeled compounds in biochemistry, biology, chemistry, etcetera
  - tracer studies (”labeling”)
  - analytical work
  - synthesis of radio-labeled compounds
  - in vitro studies
  - in vivo studies
  - field studies
  - Veterinary practise

Users of 'Unsealed' RAM

- License types with related inspection issues
  - academic (teaching/training)
  - manufacturing of radiochemicals
  - radiopharmacy
  - veterinary medicine
  - analysis as a service to others
  - clinical RIA laboratories
  - decontamination and decommissioning
  - cyclotron radiochemical production

Performance of Inspections

- Observe Licensed Operations
- Interview Licensee Personnel
- Make Independent Measurements
- Review Representative Records

STRIKE A GOOD BALANCE

Inspection Focus Elements (FE)

- 1. Security / Prevent Loss of Licensed Materials
- 2. Maintain Shielding of Licensed Materials
- 3. Comprehensive Safety Measures
- 4. Radiation Dosimetry Program
- 5. Radiation Instrumentation
- 6. Knowledgeable Workers
- 7. Management Systems & Oversight

‘Unsealed’ Inspections and FE 1

FE 1 Security/Prevent Loss of Licensed Materials

- **access to facility, control of laboratories:** facility or labs or both may be limited access (locked or attended and persons trained); other alternatives are possible
- **storage and control of materials:** secured/attended
- **user responsibilities and knowledge:** appropriate for types and quantities of RAM
- **receipt/transfer/inventory:** user records, facility records

Secured - locked and posted gates

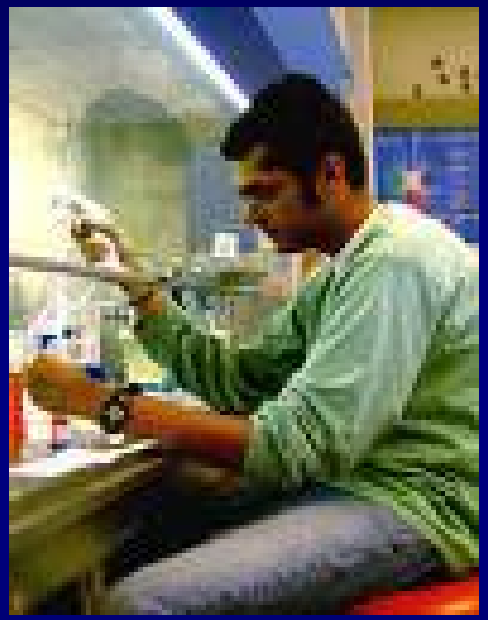
Secured – storage cage

Secured – Lock box

Secured – safe (when locked)

Control/Surveillance - Attended

Control/Surveillance - Attended



Control/Surveillance – Unattended?

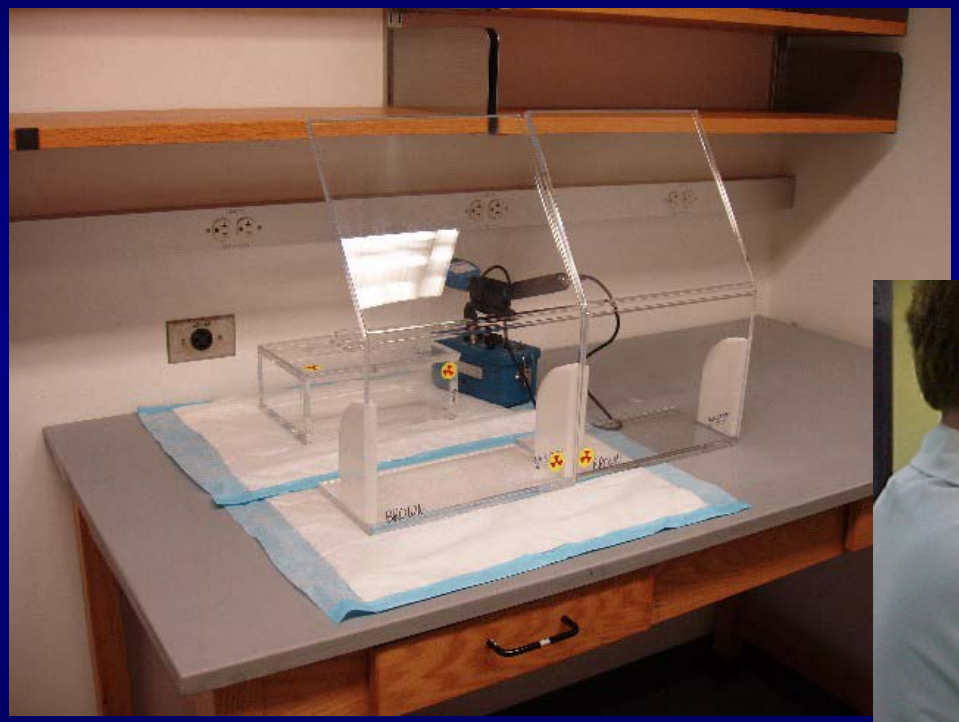
‘Unsealed’ Inspections and FE 2

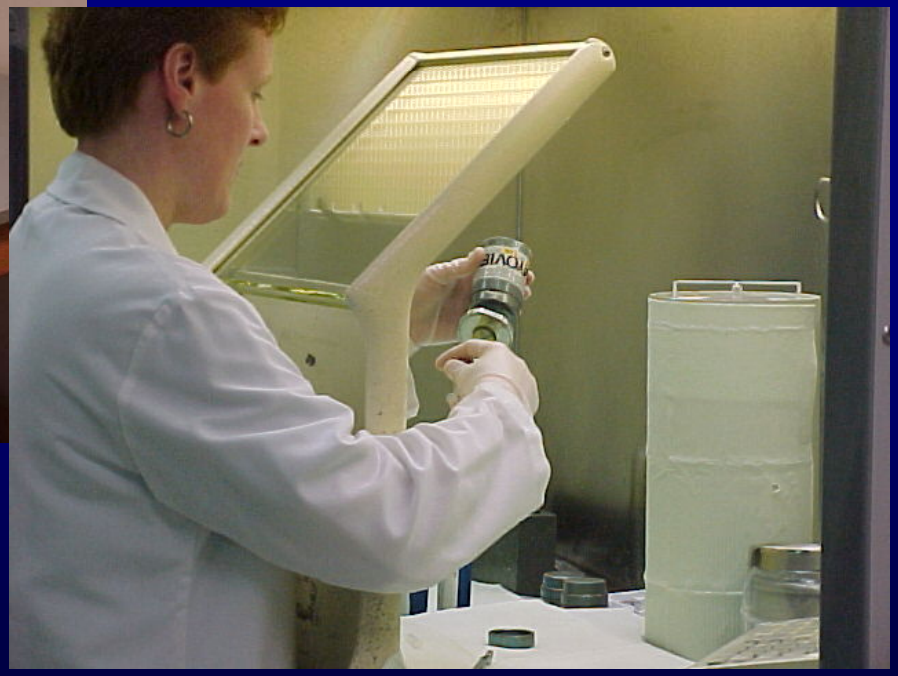
FE 2 Maintaining Shielding of Licensed Materials

- **Shielding alpha vs beta vs gamma:** mostly betas so typically see plastic shielding; look for shielding appropriate to RAM type

- **contamination controls depend on types, forms, quantities, and procedures performed:**
  - most potentially airborne CHIPPS (gases, volatile liquids, powders) used on benches or in hood; hot cells or glove boxes used for large quantities
  - absorbent liners, trays, impervious surfaces
  - Good housekeeping habits

Shielding – beta or gamma?





Shielding – beta or gamma?

Contamination Control
- hood, bench paper, survey meter

Contamination Control – spill tray under refrigerator

Contamination Control
- tacky mat, shoe covers

Contamination Control
- parafilm covering on handles

‘Unsealed’ Inspections and FE 3

FE 3 Comprehensive Safety Measures

- **materials used within operational limits:** typically not a big concern with unsealed RAM but there may be unusual situations

- **other industrial/chemical/biological/etcetera hazards considered:** the non-radiation hazards are dictated by the chemical compound which is radiolabelled and the context of the laboratory work – presence of oxidizers, flammables, carcinogens, teratogens, mutagens, bacteria, and the like!

Typical CHIPS bench

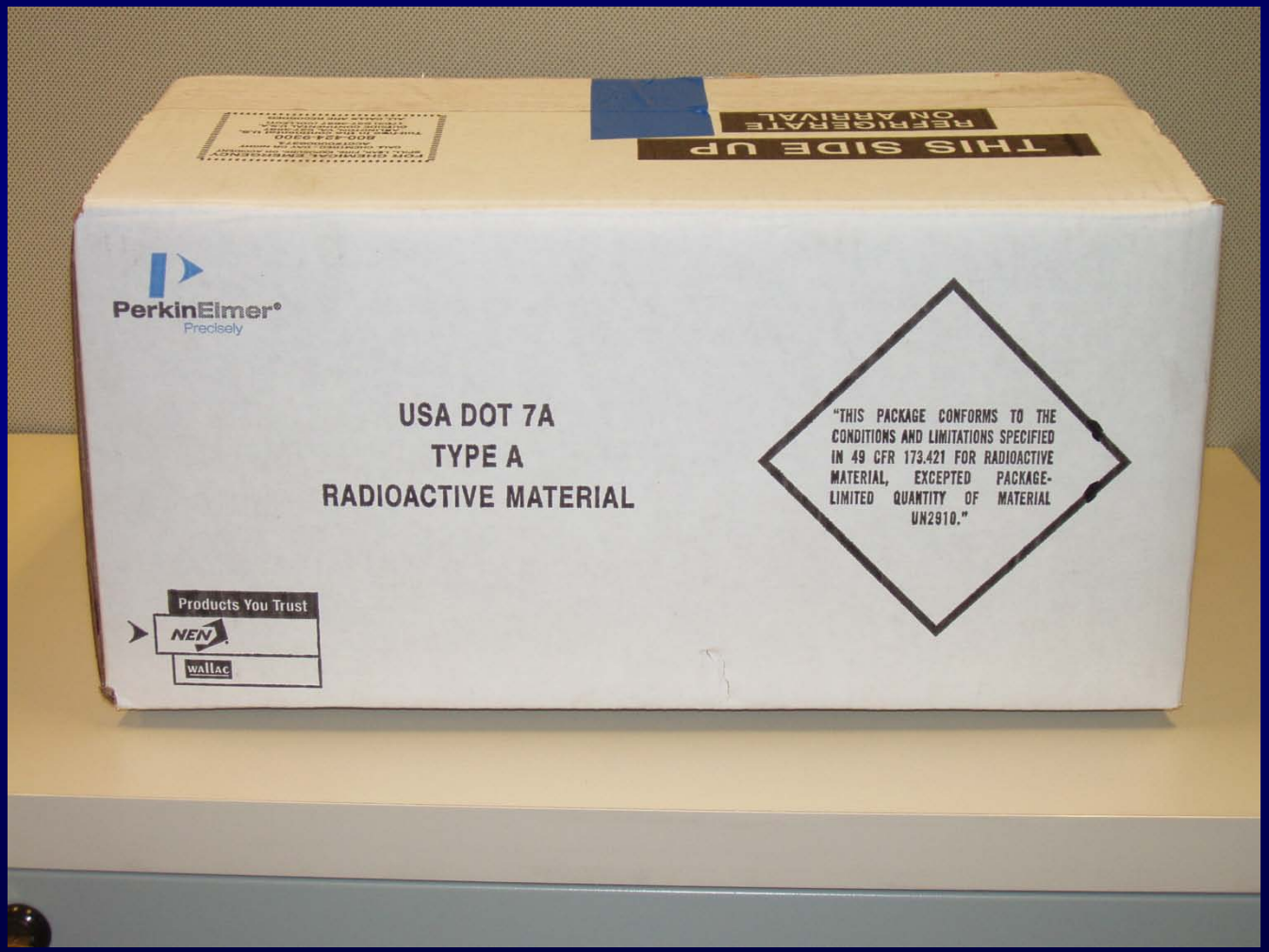
Other Hazards

‘Unsealed’ Inspections and FE 3

FE 3 Comprehensive Safety Measures

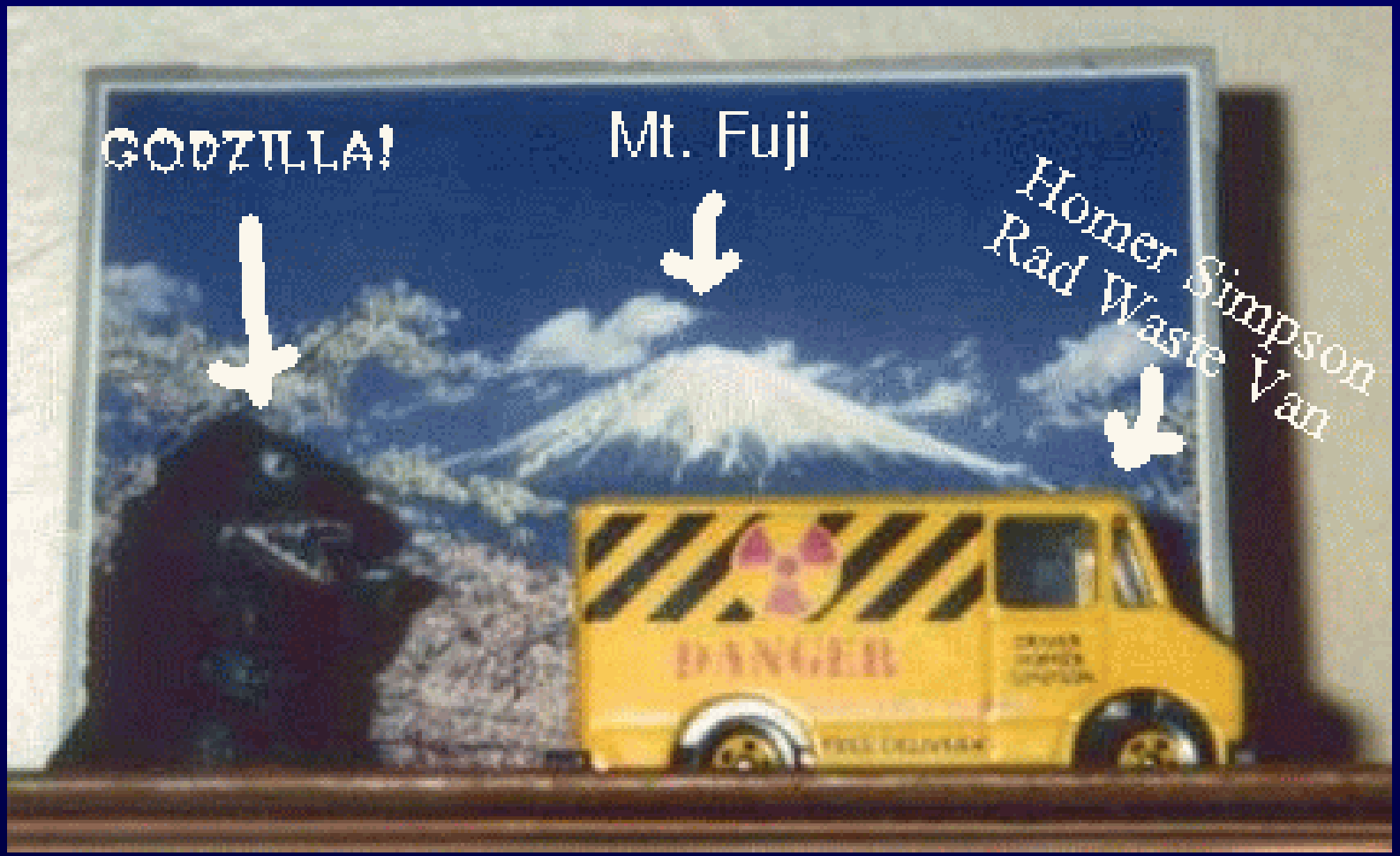
- **Transportation**
  - **iaw DOT regulations:** most CHIPS users do little shipping and are unfamiliar with DOT regulations
  - **public roads versus private roadways:** look for transfers of materials between users, especially if they are in different buildings…DOT regulations may or may not apply

Common CHIPS Shipping Box



Most common CHIPS shipment: radwaste drums, ready to go

Be alert for un-common issues.



‘Unsealed’ Inspections and FE 4

FE 4 Radiation Dosimetry Program

- **External exposure:**
  - External dosimetry is typically not required by regulation for CHIPS users (may be required by facility policy)
  - If used, look for proper use and storage of dosimeters (whole body, ring, others as needed)

External Dosimeters

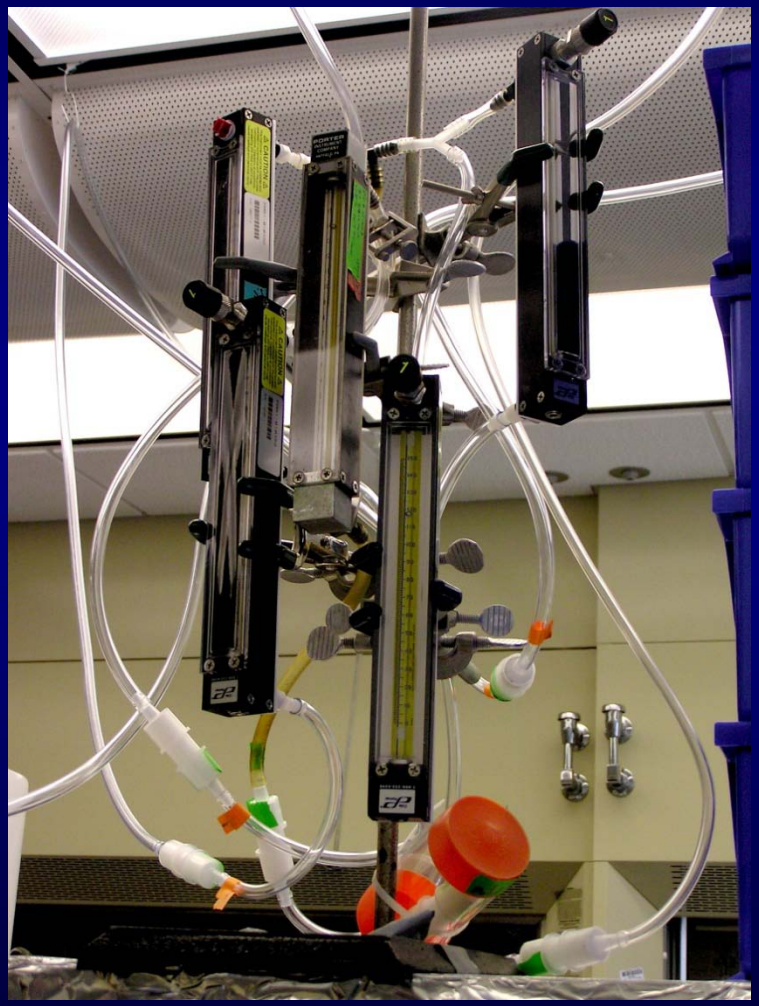
Unsealed Inspections and FE 4

FE 4 Radiation Dosimetry Program

- **Internal exposure:**
  - Internal dose assessment is typically not required for CHIPS users
  - If used, look for appropriate procedures and analysis depending on compound and radionuclide (typically urinalysis for H3, thyroid assay for radioiodines…)
  - beware of "GIGO" – poor sample collection won't be improved by complex computer dose models

Thryoid Bioassay System

Personnel Monitoring
Area Air Sampler

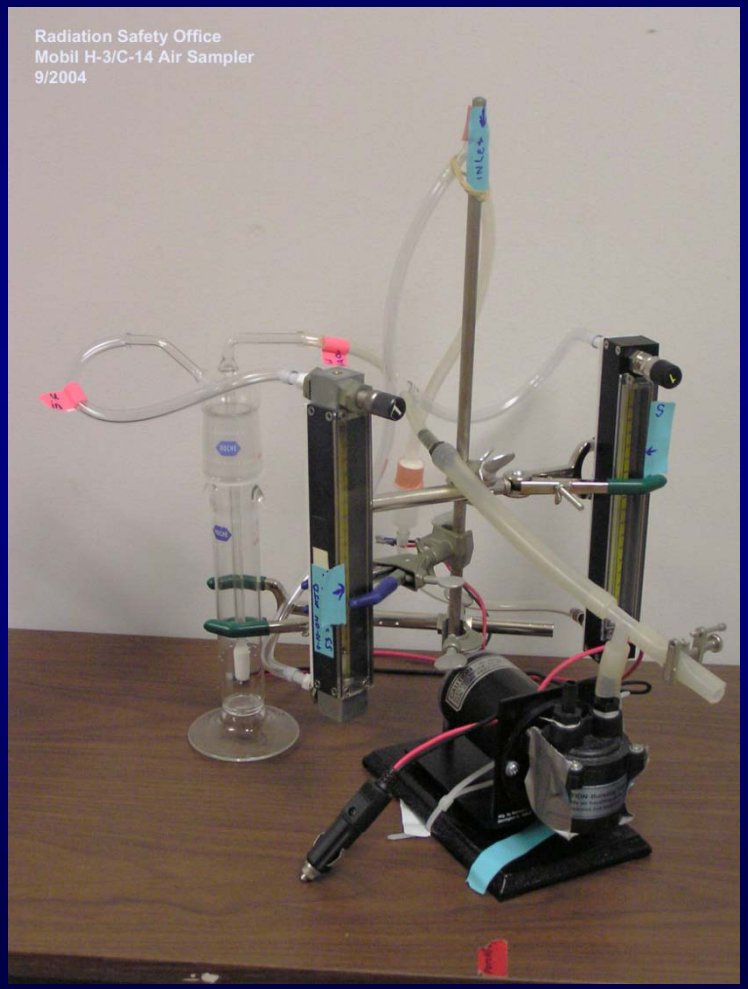


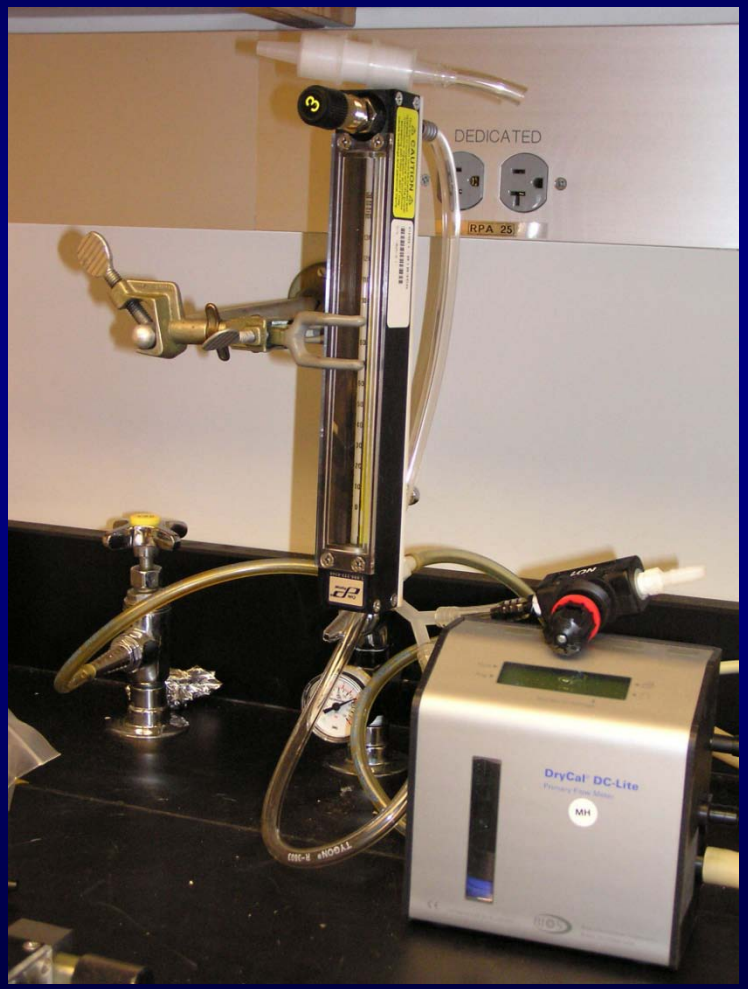
‘Unsealed’ Inspections and FE 4

FE 4 Radiation Dosimetry Program

- **public dose assessment MUST be done and recorded**
  - **Dosimetry:** location of area monitors, assumptions for total/max public doses; and/or
  - **Effluent monitoring:** location of samplers, type of sample, collection time/volume/etc; and/or
  - **Calculations:** EPA Comply code, other; and/or
  - **Surveys:** appropriate instruments, locations, assumptions

Left: Effluent air sampler for H3, C14
Right: Calibrating a rotameter





‘Unsealed’ Inspections and FE 4

FE 4 Radiation Dosimetry Program

- **preventive activities**
  - **radiation/contamination control: surveys**
    - who (lab staff or HP staff or both),
    - what type (qualitative or quantitative; contamination or radiation levels),
    - when (after each use, daily, weekly, etc),
    - where (work areas, “cold” and public areas),
    - why (habit, policy, requirement, incident),
    - how (have them demonstrate!!!), and
    - what follow-up is done

‘Unsealed’ Inspections and FE 4

FE 4 Radiation Dosimetry Program

- **preventive activities**
  - **sealed source leak tests, inventory:** do a “scavenger hunt”; review licensee follow-up to any leaking sources or lost/missing sources
  - **process controls:** typically found in synthesis labs or manufacturing – review, understand, determine if/how they could fail. Examples: tritium recycling in manufacturing; $^{14}CO_2$ control in synthesis; iodination mini-hood use.

‘Unsealed’ Inspections and FE 4

FE 4 Radiation Dosimetry Program

- **preventive activities**
  - **use of protective clothing:** routine lab safety (lab coats, gloves, safety glasses etc); occasional special needs (static-free safety shoes, clean-room dress-out, lead aprons/gloves, etc)
  - **Good housekeeping:** absorbent paper, washable trays, disposable pipetter tips etc, regular cleaning, segregated RAM work areas and equipment
  - **respiratory protection program:** not typical; if used, do appropriate prep for inspection

‘Unsealed’ Inspections and FE 4

FE 4 Radiation Dosimetry Program

- **preventive activities**
  - **waste management:**
    - decay-ins-storage (DIS) for P32 and others – have them demonstrate surveys
    - sewerage disposal – must be soluble or biological dispersible
    - Solid waste transfer to burial site – watch for compacting, crushing, and other treatments
    - Less typical – effluent releases (evaporation, oxidation, NPDES permitted discharges), incineration, 20.2002 alternates

‘Unsealed’ Inspections and FE 4

FE 4 Radiation Dosimetry Program

- **preventive activities**
  - **able to detect/assess radiation and contamination:**
    - good survey technique
    - correctly read meter face
    - Appropriate use of “cpm” versus “dpm”
  - **able to identify and investigate events:**
    review/discuss surveys/inspections/audits - do they identify events, how do they follow-up?

FE 4 good practice: contamination control

FE 4 good practices

- Do routine survey
- Wear lab coat
- Wear whole body dosimeter
- Wear ring dosimeter
- Use bench paper
- Use beta shielding
- Label ‘rad-use’ items
- Designated waste container
- Decon materials available

‘Unsealed’ Inspections and FE 5

FE 5 Radiation Instrumentation

- **Observe/check for sufficient number and types**
  - appropriate, available, operable, used (properly)
  - may be for detection and/or measurement
  - may need portable and/or analytical lab instruments
  - other equipment: air samplers, rotometers, liquid samplers, bioassay collection, etcetera

- **Test or have demonstrated**
  - Do comparative survey measurements
  - Analyze split or comparative samples

‘Unsealed’ Inspections and FE 5

FE 5 Radiation Instrumentation

- **Laboratory measurement instrumentation**
  - sufficiently sensitive: check MDA/LLD
  - calibrated for required geometries
  - QA/QC programs where applicable
- **Calibration**
  - Frequency, including maintenance of instruments
  - compare measurements
  - ***Calibrated by licensee: check/observe their procedures, facilities, calculations and results***

Survey meters
…something old…

…something new…

…some things calibrated…

…and instruments, too

‘Unsealed’ Inspections and FE 6

FE 6 Knowledgeable Workers

******* OBSERVE, ASK, VERIFY *******

- **General Training**
  - Initial training scope, method(s), testing
  - Refresher frequency, method(s)
- **Operating and Emergency Procedures**
  - real incidents (typically spills or contamination)
  - Ask about hypothetical situations
- **Posting and Labeling**
  - typical problem: C-RAM versus Rad Area

Observe / Ask Questions

Observe / Ask Questions

Observe / Ask Questions

Perform Independent Surveys

‘Unsealed’ Inspections and FE 7

FE 7 Management Systems and Oversight

- The licensee is responsible for the radiation protection program; senior management delegates authority to RSO to implement
- Management focus should include: awareness of events; safety and compliance; providing adequate resources; human performance issues; communications with the NRC

***INTERVIEW MANAGEMENT ***

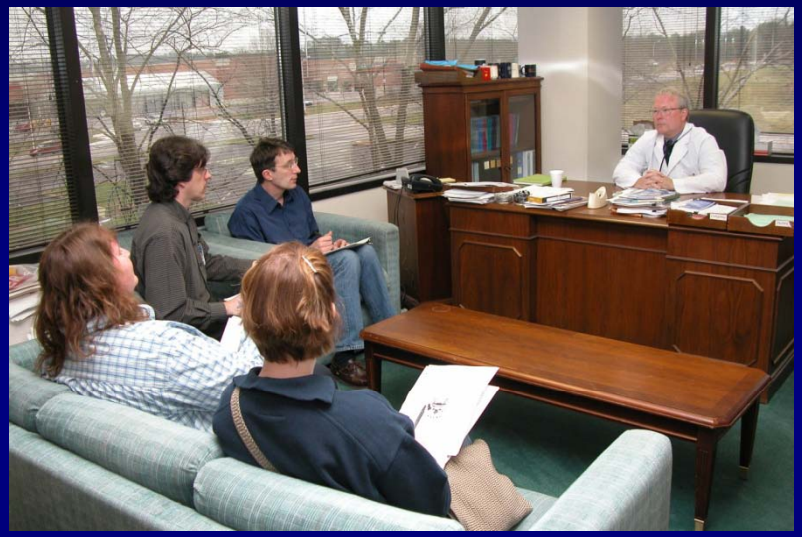
‘Unsealed’ Inspections and FE 7

FE 7 Management Systems and Oversight

- **May include a Radiation Safety Committee**
  - required for Type A broad scope
  - may be part of licensee’s safety management Structure without being part of license
    *** INTERVIEW THE RSC MEMBERS ***
- **RSO**

- **Annual Program Review and other audits**
  - Review/understand licensee’s review program; may be internal or external, annual or segmented

Meet with management



During the 'Unsealed' Inspection

Entrance with RSO

- **Discuss current scope of program:** most R&D/lab programs are getting smaller – fewer users, smaller quantities
- **Ask about activities happening during the inspection:** CHIPS use is typically sporadic, catch what you can
- **State your inspection goals and set your inspection schedule:** typically 2-4 hours for small facility (10 or fewer labs) to 1-2 days for an active Type A broad scope program

During the ‘Unsealed’ Inspection

In the Laboratories

- Observe general conditions and specific activities
- Talk to researchers, techs, and ancillary staff
- Ask for demonstrations
- Perform surveys

During the ‘Unsealed’ Inspection

In the Laboratories

- Be alert for radiation-related activities, signs, discussions etc.
- Pay attention to activities of concern or interest
- Follow up on issues; address concerns immediately

During the ‘Unsealed’ Inspection

In the Laboratories

- **Keep yourself safe**
  - follow licensee’s safety requirements: protective eyewear, lab coats, booties, etc
  - use your survey instrument [keep audio on] and wear your dosimetry
  - Be aware of potential hazards other than radiological

During the 'Unsealed' Inspection

In the Laboratories

- **Let the licensee handle the licensee's equipment**
  - licensee staff should be familiar with the equipment and how to use it; you can observe the level of radiation safety knowledge and equipment use
  - you avoid the potential of being contaminated by handling licensee equipment
  - you avoid the potential of damaging licensee equipment

During the 'Unsealed' Inspection

In the Laboratories

- **Observe "flow" of RAM:** typically arrives in Receiving; RSO notified, surveys, and delivers to users; users generate product and waste; RSO disposes of RAM waste.
- **Is what you see authorized?** Acceptable? What is "Safety" and what is at "Risk"? Follow cues and clues.
- **Check security:** test doors, locks, real and hypothetical responses; have licensee open refrigerators etc.

During the 'Unsealed' Inspection

In the Laboratories

- **Determine worker familiarity with use of protective clothing, dosimetry, and safety equipment:** typically more than adequate at commercial facilities, but not as rigorously observed at universities
- **Observe if separate areas are used for food, beverages, smoking, etc (NOT in labs)** Ditto above.
- **Determine if procedures are practices:** typically through demonstration because use is intermittent.

During the ‘Unsealed’ Inspection

In the Laboratories - Areas of Attention

- **Routine surveys - area surveys; contamination surveys; personnel protection and monitoring:**
  - usually the responsibility of lab staff, after each use/end of day, in work areas, for contamination control
  - Surveys ‘of record’ may be responsibility of Health Physics staff at quarterly, monthly, or other intervals

During the ‘Unsealed’ Inspection

In the Laboratories - Areas of Attention

- **Special surveys - monitoring, sampling and analysis of effluents (air & water) for RAM; internal dose assessment; waste collection/disposals; equipment releases for unrestricted use; facility releases/decommissioning:**
  - typically the responsibility of the Health Physics staff at larger facilities, or contracted to HP consultants or other expert staff.

During the 'Unsealed' Inspection

In the Laboratories - Areas of Attention

- **Sealed sources:** CHIPS users typically have check sources for survey meters or analytical equipment; Ni-63 ECD in gas chromatograph; Co-57 or Fe- 55 in XRF devices; at universities, may also find mossbauer sources, radioactive ores, fission foils, PuBe sources, self-shielded irradiators, calibrators, and old and new sources you've never seen before.
  - **observe/ review uses, procedures and practices**
  - **observe security and controls**
  - **inventory: do a "scavenger hunt"**

During the ‘Unsealed’ Inspection

In the Laboratories - Areas of Attention

- **Documentation in Labs:**
  many CHIPS licensees require that users maintain certain records in their labs (typically receipt records, inventory/use logs, ‘daily’ survey results, and waste tags or disposal logs).

  - **Review method, frequency, units & action levels:**
    larger facilities have required logs/forms for users
  - **Confirm if records are “official” or “unofficial”:**
    larger facilities have lab staff keep “unofficial” records while HP staff performs surveys of record

During the 'Unsealed' Inspection

In the Laboratories – Inspector Performs Surveys

- **Bring the right instrument(s):** GM for most labs, LEG for I125/P32, microR for outdoor surveys
- **Keep them on:** use the audio in labs – watch your probe so you don't bump into expensive licensee equipment; turn audio off in public areas.
- **Perform surveys correctly**
- **Watch and listen**

During the 'Unsealed' Inspection

In the Laboratories – Inspector Performs Surveys

- **Confirmatory measurements:** re-survey areas the licensee already did, and compare results; also often done after a licensee decommissioning final status survey; may include radiation level surveys, contamination surveys, analysis of water, soils or other.
- **Non-radiological measurements:** in CHIPS labs, may check such items as hood face flow rates, air sampler flow rate, sample volumes, etcetera that may impact radiological calculations

During the ‘Unsealed’ Inspection

Areas of Concern - Volatile or Airborne RAM

- **Use of unbound I-125 or I-131:** can volatilize to iodine gas at low pH/warm T and lead to uptakes; however, very few CHIPS users perform iodinations anymore.
- **Bioassays:** GIGO
- **Fume hoods or other containments:** if cluttered, do not function properly to contain airbornes
- **Effluent Surveys:** can be difficult to do properly

During the ‘Unsealed’ Inspection

Areas of Concern - High Energy Beta Emitters

- P-32 - 1.71 MeV_{max} (most common)
- Rb-86 - 1.78 MeV_{max}
- Sr/Y-90 - 2.27 MeV_{max}

- Exposure from one ml "drop" of P-32 on 1 cm^2 of skin will exceed the skin dose limit (50 Rem shallow dose-equivalent) in 85 seconds

Source: NEN package insert

During the 'Unsealed' Inspection

Areas of Concern - High Energy Beta Emitters

- **Special Handling Procedures:** look for low density (low "Z") shielding, surveys with pancake or LEG
- Use of millicurie quantities no longer common, but if millicurie quantities are used, good practices include use of:
  - DOUBLE gloves
  - Extremity monitoring > 1.0 mCi
  - Eye protection > 10 mCi

During the 'Unsealed' Inspection

Areas of Concern - RAM in Animals

- **Research Animals:** CHIPS users typically use mice, rats, or rabbits; atypically fish, roaches, poultry, etc. Medical research may use dogs, pigs, and primates. Most animals are sacrificed at the end of the study.
  - **Cages:** security, decontamination
  - **RAM pathways:** excreta, including breath ($^{14}CO_2$)
  - **precautions during handling:** wiggling animals + "sharps": not a good combination!
  - **AND TRAINING!!**

During the 'Unsealed' Inspection

Areas of Concern - RAM in Animals

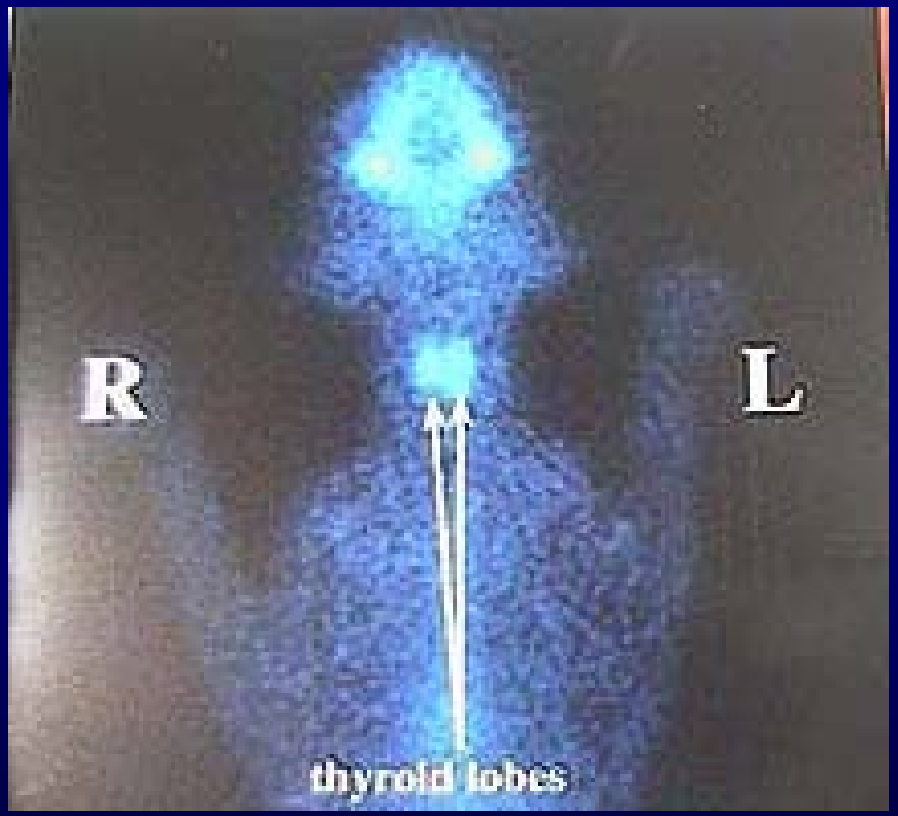
- **Veterinary Use:** Currently treat horses, cats, and occasionally dogs; these animals are returned to the owners after treatment.
- **Animal release criteria = public dose criteria of100 mrem in 1 year AND 2 mrem in 1 hour:** Review how they ensure dose limits are met.
- **Release instructions to owners:** Review the instructions, determine how they ensure owners will follow the instructions.

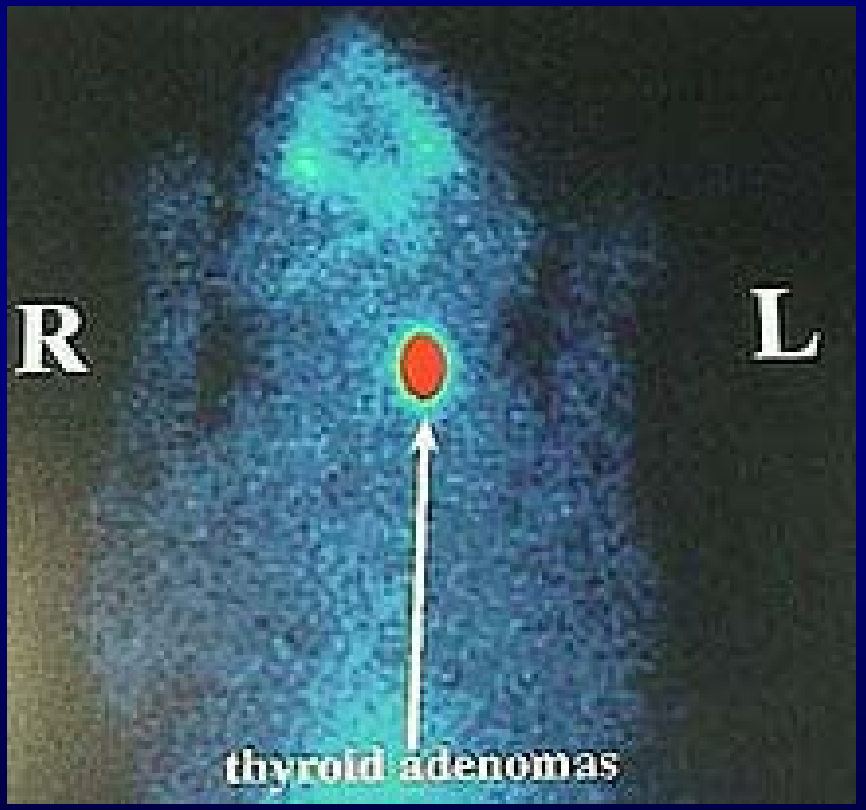
During the 'Unsealed' Inspection

Areas of Concern - RAM in Animals

- **I-131 in cats for treatment of hyperthyroidism**
  - **fairly common, increasing**
  - **unit doses ~ 3-5 mCi per cat**
- Review cat care and handling procedures
- Observe (demonstrated) release surveys
- Observe/review survey procedures and results – any spills etc that might require bioassay

Normal (left) and abnormal (right) feline thyroids





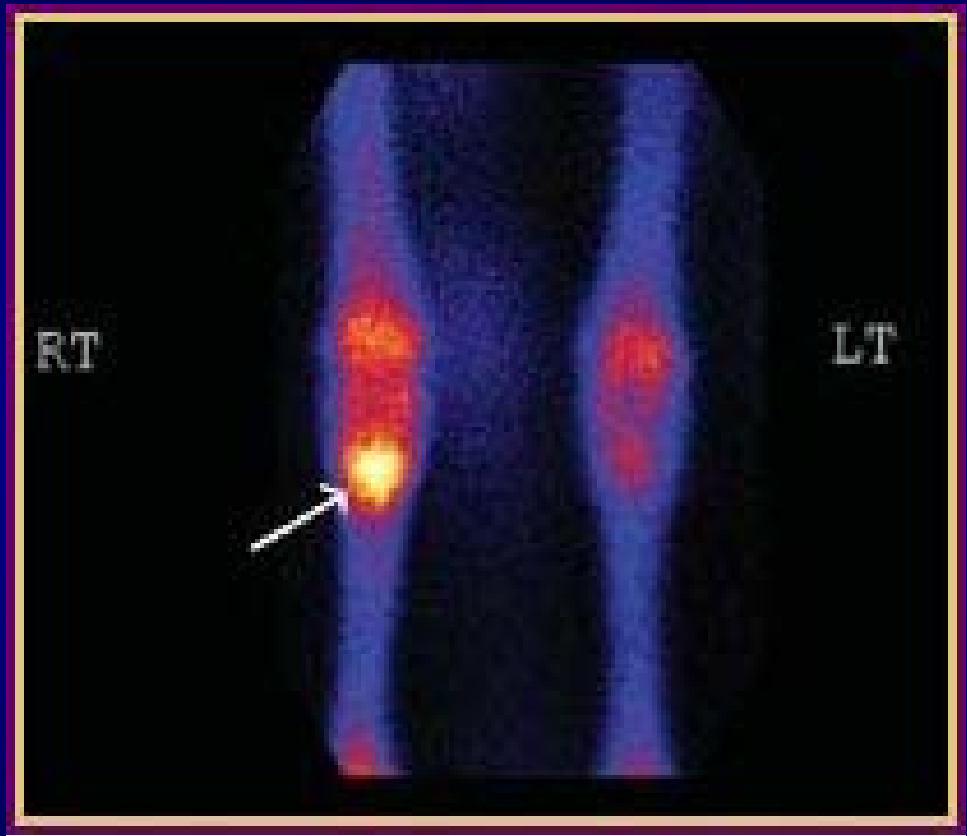
During the 'Unsealed' Inspection

Areas of Concern - RAM in Animals

- **Tc-99m in horses for bone scans (and some other)**
  - **unit doses ~ 100-250 mCi per horse**

- Observe radiation area controls in stall/stable area.
- Observe contamination controls (includes horse)
- Observe handling procedures during injection, during horse care activities, and during scan
- Look for dosimetry (whole body and ring), protective clothing, preparation for incidents
- Observe release surveys/owner instructions

Equine bone scan



Study of an avulsion fracture at the origin of the suspensory ligament. Note the yellow/white area represents the "hot spot" (problem area)

During the ‘Unsealed’ Inspection

Areas of Concern - Waste Management

- **Decay-in-Storage (DIS)**
  - **T½ < 120 days only**
  - **remove/obliterate labels**
  - **NRC: no minimum hold time**
  - **good procedures for survey prior to release**
  - **appropriate survey meter used**
  - **not distinguishable from background**
  - **waste segregation**

During the 'Unsealed' Inspection

Areas of Concern - Waste Management

- **[Public] Sanitary Sewer Disposal**
  - soluble or readily dispersible (IN 94-07 defines solubility)
  - Quantities and concentrations [10 CFR 20.2003(a)(4) and Appendix B]

- **20.2005 specific wastes "de-regulated"**
  - ≤ 0.05 μCi H-3 or C-14/gram LSC fluid
  - ≤ 0.05 μCi H-3 or C-14/gram of animal tissue

During the ‘Unsealed’ Inspection

Areas of Concern - Waste Management

- Compactors and crushers
- Incinerators and Ash (P&GD 8-10, 7 January 1997)
- Long-term storage
- Mixed Wastes

During the 'Unsealed' Inspection

Review Records

- **representative samples**
- **cross-check records**
  - **"vertical" (across record types):** find an item received, look for the use record and disposal record
  - **"horizontal" (within record type):** review all receipt records to understand what they typically are using, and looking for unusual orders
- **verify information observed in laboratories:** Example - write down names of individuals in labs then cross-check their training, ordering and dosimetry records

During the 'Unsealed' Inspection

Review Records

- **RSC minutes:** usually provide a good summary of current activities and issues
- **Incidents and events:** ask for these not-required records; they can be very informative; in some CHIPS facilities, ANY contamination is an event.
- **Worker dose, public dose**
- **Annual Program Review:** NOT an audit but can include audits...most CHIPS users do these.

Performing an Effective Exit

- **PREPARE for the exit**
  - **take time to organize your presentation:** this is especially important for multi-day inspections with a wide range of activities
  - **be sure of your findings:** know your basis, have your data, review understanding with licensee staff
  - **use notes:** stay organized, use a logical order

Performing an Effective Exit

- **Pre-brief the RSO (and staff):**
  - ensures the RSO is aware of all your findings
  - allows the HP staff to ask questions/clarify issues (and the HP staff does not usually attend the exit)
  - allows discussion of major and minor issues in technical detail, including issues that will not be discussed at the exit
  - acts as a dress-rehearsal for the inspector

Performing an Effective Exit

- **Exit with the highest possible level of management:** Be aware that at large commercial firms and universities, managers may not be scientists, so tailor your discussions to minimize unnecessary technical detail.
- **Explain the inspection process and any follow-up**
- **Discuss what you found**
  - opportunity to highlight positive findings
  - give perspective to negative finding
  - Be open; accept comments; answer questions

Questions???

THE END